DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 5, 2014

Stryker Orthopaedics
Karen Ariemma
Senior Strategic Regulatory Affairs Manager
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K141056
Trade/Device Name: Triathlon Knee System, Triathlon Tritanium Tibial Baseplate, Triathlon Low Profile Tibial Tray, Triathlon Metal Backed Patellar
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: April 24, 2014
Received: April 25, 2014

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141056

Device Name: Triathlon Knee System

Indications for Use:

General Total Knee Arthroplasty (TKA) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture -management techniques.

The Triathlon® Tritanium® Total Knee System components are indicated for both uncemented and cemented use.

The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.

The Triathlon® All Polyethylene tibial components are indicated for cemented use only.

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure accompanied by bone loss.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

Indications for Use

510(k) Number (if known): K141056

Device Name: Triathlon Tritanium Tibial Baseplate

Indications for Use:

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques

Additional General Total Knee Arthroplasty (TKR) Indications specific to the PS implant:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint
- Absent or non-functioning posterior cruciate ligament
- Severe anteroposterior instability of the knee joint

The Triathlon Tritanium Tibial Baseplates are indicated for both cemented and uncemented use.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

Indications for Use

510(k) Number (if known): K141056

Device Name: Triathlon Low Profile Tibial Tray

Indications for Use:

The Triathlon Low Profile Tibial Tray is intended to be used with commercially available Triathlon® femoral components and associated patellar components, and tibial bearing inserts in primary cemented total knee arthroplasty. The indications for the Triathlon® Low Profile Tibial Tray are outlined below:

Indications for Use:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

Indications for Use

510(k) Number (if known): K141056

Device Name: Triathlon Metal Backed Patellar

Indications for Use:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;
- Post traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee.

These products are intended to achieve fixation without the use of bone cement.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

510(k) Summary

Sponsor Stryker Orthopaedics
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Date Prepared: June 20, 2014

Proprietary Name: Triathlon Knee System

Common Name: Total Knee Joint Replacement

Classification Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis. (888.3565)
Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560

Product Codes: MBH, JWH

Legally Marketed Device to Which Substantial Equivalence is Claimed: Triathlon Knee System components cleared via the following 510(k) submissions: K031729, K042067, K042883, K042993, K050539, K051146, K051380, K053514, K061521, K062037, K063423, K070095, K072221, K072575, K123166, K123486, and K13262.

Device Description:

The devices covered by this submission include femoral components, tibial baseplates, tibial inserts, all-polyethylene tibial components, patellar components, metal backed patellar components, tibial and femoral augments, stems, stem extenders and offset adaptors used in total knee arthroplasty procedures. All devices have been previously determined substantially equivalent in prior 510(k) submissions and are commercially available. The Triathlon Knee system components are manufactured from the following materials Cobalt Chromium Alloy, Titanium Alloy, Commercially Pure Titanium, Ultra-High Molecular Weight Polyethylene and Calcium Phosphate.

The purpose of this submission is to modify the labeling of the Triathlon Knee System to revise the contraindications.

Indications:

There are no changes to the previously cleared indications for use.

Triathlon Knee System

General Total Knee Arthroplasty (TKA) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture -management techniques.

The Triathlon® Tritanium® Total Knee System components are indicated for both uncemented and cemented use.

The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.

The Triathlon® All Polyethylene tibial components are indicated for cemented use only.

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Triathlon Tritanium Tibial Baseplate

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis

- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques

Additional General Total Knee Arthroplasty (TKR) Indications specific to the PS implant:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint
- Absent or non-functioning posterior cruciate ligament
- Severe anteroposterior instability of the knee joint

The Triathlon Tritanium Tibial Baseplates are indicated for both cemented and uncemented use.

Triathlon Low Profile Tibial Tray

The Triathlon Low Profile Tibial Tray is intended to be used with commercially available Triathlon® femoral components and associated patellar components, and tibial bearing inserts in primary cemented total knee arthroplasty. The indications for the Triathlon® Low Profile Tibial Tray are outlined below:

Indications for Use:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.

Triathlon Metal Backed Patellar

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;
- Post traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee.

These products are intended to achieve fixation without the use of bone cement.

Summary of Technological Characteristics: There have been no changes to the technological characteristics of the Triathlon Knee System as a result of the revision to the labeling. The subject devices have the same design and are manufactured from the same materials as the predicate devices.

Non-Clinical Testing: Performance testing was not required in support of this submission because this submission covers a labeling modification to the contraindications.

Clinical Testing: Clinical testing was not required as a basis for substantial equivalence.

Conclusion: The Triathlon Knee System components are substantially equivalent to the predicate devices identified in this premarket notification.